HASS CORPORATION

K111573

510(k) Summary

AUG 2 6 2011

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 05/20/2011

1. Submission Sponsor

	Submitter
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2. Submission Correspondent

LK Consulting Group
951 Starbuck St. Unit J,
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Priscilla Chung
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Email: info@LKconsultinggroup.com

3. Device

Trade Name: MonoBloc BM Series
Common Name: Dental Frame Material for Dental Prosthesis
Classification Name: Porcelain Powder for Clinical Use
Classification regulation: 21 CFR 872.6660
Product Code: EIH

2. Predicate Device:

VITABLOCS® Mark II (K022408) by Vita zahnfabrik Gmbh&Co.KG
Glass Ceramics (K053438) by 3M ESPE AG

3. Description:

MonoBloc BM Series is glass type material used for aesthetic purposes of inlays, onlays, veneers and crowns. This looks like a block form and corresponds to ISO

6872 Type 2 Class 1. It can be fabricated using dental CAD/CAM devices such as CEREC™ inLab and CEREC™ MCXL.

4. Indication for use:

MonoBloc BM Series is indicated for use as a dental restoration including inlays, onlays, veneers, and crowns.

5. Safety and Effectiveness:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intend use and different technological characteristics, and it can be demonstrated that the device as safe and effective as the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 5109(K) submission that the differences between the MonoBloc BM Series and the predicate devices do not raise any questions regarding its safety and effectiveness.

6. Physical Characteristics

The following properties were tested according to ISO 6872 and 9693 and the all results met the test criteria.

- ISO 6872 - Uniformity, Extraneous materials, Chemical Solubility and Flexural Strength
- ISO 9693 - Linear Thermal Expansion and Glass Transition Temperature

7. Conclusion

Based on the information provided in this premarket notification, MonoBloc BM Series is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hass Corporation
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group
951 Starbuck Street, Unit J
Fullerton, California 92833

AUG 26 2011

Re: K111573
Trade/Device Name: MonoBloc BM Series
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 31, 2011
Received: June 6, 2011

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111573

Device Name: MonoBloc BM Series

Indications for Use:

MonoBloc BM Series is indicated for use as a dental restoration including inlays, onlays, veneers, and crowns.

Prescription Use __√__		**Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D)	**AND**	**(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEE DED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111573